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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/651,307	08/28/2003	Chia-Gee Wang	U 014776-3	9029
140	7590	08/28/2007	EXAMINER	
LADAS & PARRY 26 WEST 61ST STREET NEW YORK, NY 10023			HUGHES, ALICIA R	
			ART UNIT	PAPER NUMBER
			1614	
			MAIL DATE	DELIVERY MODE
			08/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/651,307	Applicant(s) WANG, CHIA-GEE	
	Examiner Alicia R. Hughes	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 115 and 122-135 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 115 and 122-135 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims and Examination

Claims 115 and 122-135 are pending and the subject of this Office Action.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicants' arguments filed on 10 August 2007 have been fully considered but are deemed to be persuasive regarding the previous rejection. Rejections not reiterated from this Office's previous action are hereby withdrawn. The rejections set forth herein constitute the complete set of rejections being applied to the instant application presently.

Claim Rejections - 35 U.S.C. §112.1

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 115 and 122-135 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As a result, the

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effect of performing the invention by one skilled in the art would be that of undue experimentation.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in organic chemistry is high, the results of experiments to discover treatments for the illnesses and conditions recited in claim 17, is unpredictable. While all of the Wands factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The claimed invention relates to a method for selectively disrupting cells at a tumor site for a human in need thereof by administering rose bengal to the subject and thereafter irradiating the location with line emission x-rays in such a way as to cause the emission of Auger electrons from the rose bengal accumulated in lysosomes of the tumors in a dosage amount that is effective to cause a disruption of the lysosomes of the cells at the tumor/cancerous cell site.

It is known in the art and was so known at the time the instant invention was contemplated that there is no one specific chemotherapeutic agent that is effective to treat all types of cancers. Goldman et al., Cecil Textbook of Medicine, 21st Edition, pp. 1060-1074

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(2000)(See pages 1065, table 198-5; page 1066, table 198-6; page 1068, page 198-8; and page 1068, page 1071).¹ The Applicants' specification does not contain working examples demonstrative of the types of tumors contemplated to be treated/disrupted by the instant invention, and the claims are written so broadly, that they are construed as treating all types of tumors and cancers. As a result, the effect of carrying out the instant invention to a skilled artisan would be that of undue experimentation. As such, the disclosed claims are rejected for failing to meet the enablement requirement.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

¹ Cited on the PTO-892 form filed on 08 May 2006.

Claims 115, 122 and 130 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,366,801 B1 [hereinafter referred to as "Cash et al"] in view of U.S. Patent No. 5,627,871 [hereinafter referred to as "Wang"] and Ariel et al, "Treatment of Inoperable Cancer of the Liver by Intra-Arterial Radioactive Isotopes and Chemotherapy," *Cancer*, Vol. 20, No. 5, pages 793-804 (1967)[hereinafter referred to as Ariel et al"].²

The teachings of Cash et al, Wang, and Ariel et al from this Office's action of 08 May 2006 and all arguments emanating therefrom, are incorporated herein by reference, in total.

It is important to note that the radioactive iodine rose bengal disclosed in Ariel et al is reasonably acceptable as a type of rose bengal to those of skill in the art. And furthermore, the line emission X-ray treatment as set forth in the previous Office Action by way of Cash et al in view of Wang reasonably suggests that the irradiation of iodine within the rose bengal compound type, thereby providing tumor treatment, as claimed in the present invention.

This interpretation of rose bengal in claim 15 of the instant set is further supported via the iodine rose bengal type as described in instant claim 123, which depends ultimately from instant claim 115.

In light of the disclosures, one of ordinary skill in the art would be motivated to utilize rose bengal as an anti-therapeutic agent to treat cancerous tumors. Thus, the combined references teach and make *prima facie* obvious how to use the claimed invention at the time that it was made.

² Cited on the PTO-892 form filed on 08 May 2006.

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Conclusion

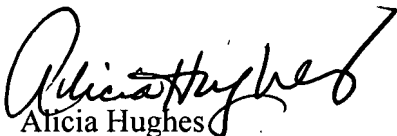
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see <http://pair-direct-uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

16 August 2007


Alicia Hughes


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER